REMARKS

Claims 1-25 are in the application. Reconsideration and withdrawal of the rejections is requested in view of the following remarks.

Claim 18 has been amended responsive to paragraph 2 of the November 16, 2004 Office Action, and to delete the characteristic dimension element. New claims 19-25 have been added. New claim 19 generally includes content of claims 1, 2, and 5. The chamber ring in claim 19 is described at 0116.

New claim 20 is similar to claim 4. New claim 21 describes the 50-90% range relative to the largest (greater characteristic dimension) bead, as supported at 0072.

New claims 22 and 23 describe the open central interior in the same plane as the bead race. See, for example, Figs. 25, 34, and 35 in the application.

New claim 24 includes elements of claim 1, and also describes a bead race wherein the bead moves primarily, but not exclusively, around the bead race upon inhalation by the patient, as at 0075.

New claim 25 includes non-uniform bead movement, as described at 0011.

Turning to the prior art, each of the independent claims 1, 18, 19, and 24 describe an inhaler including a dispersion chamber having an open central interior. See, for example, Figs. 24, 25, 32, 34, and 35 of the application. Hurka *et al.*, USP 4,841,964, describes an inhaler having an orbital path 3 surrounding a solid central area 10. See Figs. 1, 4, and 5 in Hurka *et al.* The solid central area 10 is essential in Hurka *et al.*, "... so that the ball 4 is provided with sufficient mechanical guidance..." Col. 4, lines 35-39. Consequently, Hurka *et al.* teaches away from an open central interior. The geometry of the dispersion chamber described in the claims is fundamentally different from *Hurka et al.* In Hurka *et al.*, the ball 4 is confined to the

toroidal orbital path 3. See Fig. 4. The ball 4 can only move clockwise or counter-clockwise in the orbital path 3. No inward radial or chord-like movement, or chaotic movement, can be achieved. See Hurka *et al.*, Fig. 2. The claims are therefore allowable over Hurka *et al.*

Regarding claim 6, the "non-smooth" surface described in Hurka *et al.* at col. 7, lines 35-60, may include helical grooves or other non-smooth features. However, the ball is still confined to the orbital path 3. In contrast, the chaotic movement of claim 6 allows the beads to move radially inwardly, such that they are not confined to a pure orbital path, as in Hurka *et al.*

Regarding claim 7, the dose platform is adjacent to the inlet, for example, as shown at 46 in Fig. 2 of the application. The orbital path in Hurka *et al.* is not a dose platform. In Hurka *et al.*, there is no movement of the dose from a platform or area outside of the dispersion chamber, into the dispersion chamber, as described in claim 7. In Hurka *et al.*, the particulate is apparently provided onto the orbital path during manufacture. No dose platform or other movement of powder into the orbital path is described.

With respect to claim 8, the non-smooth surface of the orbital path is provided to cause the ball to spin perpendicular to the direction of travel. Col. 7, lines 35-36. In contrast, claim 8 describes an obstruction causing the bead to move chaotically. Obstructions are shown e.g., at 54 in Figs. 2 and 3. The claimed obstructions change the direction of movement of the bead. The grooves or non-smooth surface cause the ball in Hurka *et al.* to spin. There is no disclosure in Hurka *et al.* of changing the direction of ball movement.

Turning to claim 10, Fig. 5 in Hurka *et al.* is described as a sectional elevation in exploded form. Hurka *et al.* does not otherwise appear to disclose a removable dispersion chamber.

Moving to the rejections at paragraph 22 of the Office Action, the 4000-10,000 rpm range of claim 16 reflects a mechanism of operation different from Hurka *et al.* Hurka *et al.* involves relatively large, dense, and heavy balls (e.g., glass) rolling around in the orbital path 3. Solid particles in the path are ground and dispersed, with the ball moving at a relatively low rpm. The range of claim 16 is above the rpm range suggested by Hurka *et al.*, and tends to reflect faster and different movement of lighter and smaller beads. See 0075 and 0076.

Claim 18, apart from the comments above, is also separately patentable over Hurka *et al.*, because claim 18 describes a blister supported on the inlet. None of the ways of introducing the active substance into the inhaler described at col. 8, lines 19-32 of Hurka *et al.* involve movement of the substance into the dispersion chamber, during inhalation. The difference between claim 18 and Hurka *et al.* is significant in several ways. The inhaler of claim 18 could be reused, if desired. The inhaler in Hurka *et al.* cannot. The powder in the inhaler of claim 18 is within a blister container, where it is sealed from the environment, in a very compact package. Sealing the active substance in Hurka *et al.* requires sealing the entire inhaler using the seals 9. Col. 4, lines 34-35. The airflow characteristics associated with the blister container are also different from Hurka *et al.*

New claim 19 describes a chamber ring for preventing beads from moving out of the dispersion chamber and into the outlet. The chamber ring is shown at 270, for example, in Figs. 25 and 34. Hurka *et al.* has no equivalent feature.

New claims 24 and 25 further describe bead movement out of the bead race, and non-uniform bead movement, facilitated by the open central interior. These features are not suggested by Hurka *et al.*

In new claim 21, the largest bead is 50-90% of the height of the dispersion chamber, as described at 0072. In Hurka *et al.*, in each case, the largest ball is greater than 90% of the path width. See Col. 5, lines 31-45: 3mm ball/3.1mm path width = 97%; 4mm ball/4.3 mm path width = 93%. See Col. 8, lines 53-61: 3.5mm ball/3.7mm path width = 95%; 4.1mm ball/4.3mm path width = 95%.

In Hurka *et al.*, the ball diameter must be very close (over 90%) of the path width, so that inhaled air can sufficiently propel the ball. In addition, since Hurka *et al.* relies on rolling contact to disperse the solid particles (col. 7, lines 65-67), the ball and path dimensions must be closely matched. The claimed inhaler, on the other hand, involves contact, collisions and shear effects (0075 and 0076), rather than pure rolling contact.

In view of the foregoing, it is submitted that the application is in condition for allowance. A Notice of Allowance is requested.

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Respectfully submitted,

PERKINS COIE LLP

By: Kenneth H. Ohriner
Kenneth H. Ohriner
Reg. No. 31,646

Customer No. 34055
Perkins Coie LLP
Patent - LA
P.O. Box 1208
Seattle, WA 98111-1208
Phone: (310) 788-9900
Fax: (206) 332-7198